K032094
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510(k) Summary

NOV 14 2003

Date
November 11, 2003

Submitter
Medicrea
Z.I. Chef de Baie
17000 LaRochelle, FRANCE

Contact person
J.D. Webb
1001 Oakwood Blvd
Round Rock, TX 78681
512-388-0199

Common name
Posterior pedicle screw system
Hooks
Sacral plate

Classification name
Spondylolisthesis Spinal Fixation Device System per MNH 888.3070
Pedicle Screw Spinal System per MNI 888.3070
Spinal Interlaminal Fixation Orthosis per KWP 888.3050

Equivalent Device
The components covered by this submission are exactly the same as those cleared in K001024, K012175, K013191, K013431, K013442 and K020236. These devices were all submitted by Encore Orthopedics. All of the cleared devices were designed, manufactured and packaged by Medicrea.

Device Description
The PASSmed system includes pedicle screws include polyaxial screws in a various lengths and diameters. Standard and offset height screws are available, with the offset used in cases of severe spondylolisthesis. Standard and realignment clamps are used to connect the screw and rods. Rods are Ø6mm in lengths ranging from 50mm to 250mm. It also includes sacral plates and screws. The sacral plate takes the place of pedicle screw in connecting the rod to the sacrum. The plate is attached to the sacrum with two screws. The polyaxial attachment mechanism to the rod is the same as the pedicle screws. The plates come in right and left configuration. The rod-plates are similar to the rods as they consist of a short rod segment that has enlarged portions at the ends with holes to attach directly to screw with hemispherical nuts rather than connecting to the rod via a clamp. The rods attach to the hooks and can be used for single or multiple level fixations. They have the same rod attachment mechanism as the polyaxial screws. The laminar hooks are inserted inferior and superior around the lamina, pedicle hooks are inserted inferior and superior around the pedicles.

Intended Use
The PASSmed is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

As a pedicle screw system PASSmed is indicated for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

It also includes hooks and a sacral plate indicated for degenerative disc disease (ddd) defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis and failed previous fusion.

Summary Nonclinical Tests
Testing performed according to ASTM F1717 indicate that the PASSmed system is as mechanically sound as other devices commercially available.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 4 2003

Medicrea
C/o Mr. J.D. Webb
1001 Oakwood Boulevard
Round Rock, Texas 78681

Re: K032094
Trade/Device Name: PASSmed Spinal System
Regulation Number: 21 CFR 888.3050, 21 CFR 888.3070
Regulation Name: Spinal interlaminal fixation orthosis, Pedicle screw spinal system
Regulatory Class: II
Product Code: KWP, MNH, MNI
Dated: October 10, 2003
Received: October 14, 2003

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) number (if known): K032094

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Indications for Use:

PASSmed Spinal System
Indications for Use

The PASSmed is a pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

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(PLEASE DO NOT WRITE BELOW THIS LINE– CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ OR Over-the-Counter Use ____
(per 21 CFR 801.109)

(Optional format 1-2-96) _____

for Mark N Milhous

(Division Sign-off)
Division of General, Neurological
and Restorative Devices

510(k) Number K032094